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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/668,856	09/23/2003	Bradley Michael John Stringer	2240-1-001DIV1CON1	3163

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EXAMINER

KETTER, JAMES S

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 09/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/668,856	Applicant(s) STRINGER, BRADLEY MICHAEL JOHN	
	Examiner James S. Ketter	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28-31, 35, 38-51, 54, 56-62 and 65 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 43, 45, 46, 48, 50, 51, 57-62 and 65 is/are allowed.
- 6) ☒ Claim(s) 28, 30, 35, 38-42, 44, 47, 49, 54 and 56 is/are rejected.
- 7) ☒ Claim(s) 29 and 31 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 08/836,440.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Claims 29 and 31 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claims 43, 45, 46, 48, 50, 51, 57-62 and 65 are allowed.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 28, 30, 35, 38-42, 44, 47, 49, 54 and 56 are rejected under 35 U.S.C. 102(b) as being anticipated by Stamps et al. (U, newly cited herein, previously cited in related 09/694,203, now US Patent 6,340,592. A review and update of the search of record uncovered this citation. The delay in its citation herein and in presenting the instant rejection is regretted.)

Instant claim 28 is drawn to an immortalized human cell line expressing tissue specific function comprising at least one safety means, and wherein the cell is immortalized by a retroviral construct comprising an immortalizing oncogene. Claim 30 specifies that the cell has a mature, differentiated phenotype. Claim 35 specifies that the oncogene is viral. Claim 38 specifies that the oncogene has a control means. Claim 39 further specifies that the control means is responsive to environmental conditions. Claim 40 further specifies that the oncogene and control means are integrated. Claim 41 further specifies that the control means comprises a temperature sensitive entity. Claim 42 further specifies that said entity is the integrated immortalizing oncogene. Claim 44 specifies that said oncogene is SV40 T antigen. Claim 47

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specifies that the safety means is a gene. Claim 49 is drawn to an immortalized human cell line expressing tissue specific function which further comprises at least one safety means and wherein the immortalization is by an immortalizing oncogene which is co-expressed with the safety means. Claim 54 is drawn to a homogeneous population of human cells immortalized by an immortalizing oncogene in a retroviral construct and which has a safety means. Claim 56 further specifies that the cell are for use in transplantation.


Stamps et al. teaches, e.g., as recited in the Abstract, eight cell lines derived from human breast epithelial cells which were immortalized by retroviral constructs comprising SV40 temperature-sensitive T antigen gene. Foci, i.e., homogeneous pluralities of such cells are taught. The temperature-sensitivity of the oncogene acts as a control means. With respect to limitations that the cells are for transplantation, the capacity to be transplanted would be an inherent property of the cells of Stamps et al. in that there would be no obstacle to such cells being transplanted.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James S. Ketter whose telephone number is 571-272-0770. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JSK
6 September 2006



JAMES KETTER
PRIMARY EXAMINER